OCT 12 2011

CORNERSTONE® PSR Cervical Fusion System
Interbody Fusion Device
510(k) Summary
May 2011

I. **Company:** **Medtronic Sofamor Danek**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: **Regina Holmes**
Senior Regulatory Affairs Specialist

II. **Proprietary Trade Name:** CORNERSTONE® PSR Cervical Fusion System

Classification Name: Intervertebral Body Fusion Device

Product Code: ODP (21 CFR 888.3080)

Common Name: Cervical Interbody Fusion Device

III. **Product Description**

The CORNERSTONE® PSR Cervical Fusion System consists of spacers which can be inserted between two cervical vertebral bodies to give support and correction until fusion occurs. The hollow geometry of the implant allows it to be packed with autogeneous bone graft. The CORNERSTONE® PSR Cervical Fusion System also includes instrumentation that enables the surgeon to implant the devices via an open, anterior approach.

The device sizes are available in various heights and in a 4° lordotic angle option. The implant devices are manufactured from medical grade polyetheretherketone (PEEK - OPTIMA® LT1) per ASTM F2026 and also contain either tantalum markers per ASTM F-560 or titanium alloy markers per ASTM F-136 so that the position of the implant can be determined on X-ray or other imaging.

IV. **Indications for Use**

The CORNERSTONE® PSR Cervical device is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by

radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The CORNERSTONE® PSR device is to be used with supplemental fixation. The CORNERSTONE® PSR device is also required to be used with autograft.

V. Performance Data

The following pre-clinical studies were conducted using worst case CORNERSTONE® PSR devices: static and dynamic compression, static and dynamic torsion, static and dynamic compression shear per ASTM F2077-03; subsidence per ASTM F2267-04; and expulsion. The results of these studies were found to be substantially equivalent to legally marketed devices.

VI. Substantial Equivalence

Documentation was provided which demonstrated that the subject device is substantially equivalent to the following currently marketed devices: CORNERSTONE® PSR Cervical Interbody Fusion Device (K100214, SE 6/25/2010); VERTE-STACK® Spinal System (K041197, SE 8/9/2004); PLATEAU® (PLATEAU-C) Spacer System (K093093, Life Spine, SE 10/13/2010); and BENGAL® System (K081917, DePuy, SE 5/22/2009).

VII. Conclusion

It was determined that the subject device is substantially equivalent in design, materials, function, indications for use, and scientific technology to the predicate devices presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 12 2011

Medtronic Sofamor Danek
% Ms. Regina Holmes
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K111264
Trade/Device Name: CORNERSTONE® PSR Cervical Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: September 14, 2011
Received: September 15, 2011

Dear Ms. Holmes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K111264

Device Name: CORNERSTONE® PSR Cervical Fusion System

Indications for Use:

The CORNERSTONE® PSR Cervical device is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The CORNERSTONE® PSR device is to be used with supplemental fixation. The CORNERSTONE® PSR device is also required to be used with autograft.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111264